



# Vaccine Safety Quarterly

## Brighton Collaboration Community News

**Quarter 1- 2024**

**Frederick Varricchio** , PhD, MD - *Editor-in-chief* **Nadja Vielot**, PhD - *Associate editor*

### **La Plus Ça Change**

*After five years, this will be our last edition of the Vaccine Safety Quarterly. It has been an interesting time to be editor of the VSQ. Brighton Scientific Director, Bob Chen, describes the next steps below. We are grateful to all our contributors and readers since 2020.*

Dear Brighton Collaboration members:

Our community has navigated several transitions over the past few years. In 2019 Brighton Collaboration moved from its headquarters in Basel, Switzerland to Atlanta, Georgia, USA, where it is now a program of the [Task Force for Global Health](#). The next year, we launched the [Safety Platform for Emergency vAccines \(SPEAC\)](#) project with CEPI. In 2020, our Science Board shifted its focus to addressing the safety of COVID-19 vaccines.

We would like to announce another transition. We are revamping our newsletter and the way we keep in touch with our members. Our newsletter's next issue will have a new look and more stories from the Brighton community. We invite you to [complete our survey](#) to help shape this next phase of Brighton's communications.

We thank Fred Varricchio and Nadja Vielot for their editorial leadership over the past several years. Their voluntary support and enthusiasm for the VSQ have made each issue possible. All archived issues of the Vaccine Safety Quarterly will continue to be available on our [website](#).

As Brighton Collaboration's staff continues to grow, we look forward to showcasing more voices and stories from the vaccine safety field. First, we'll introduce you to our new Research Director, [Dr. Eileen Farnon](#), who brings expertise in clinical infectious diseases, epidemiology, and industry to Brighton and the SPEAC project. Next, we share a [video about Brighton Collaboration Case Definitions](#), developed for the SPEAC project by one of our past Science Board chairs, Dr. Barb Law. We'll also direct you to our website's updated pages for [GAIA](#) and [BRAVATO](#), past and current projects that offer promising products for our field. Lastly, we invite you to engage with us on LinkedIn and follow [our page](#).

We have more exciting news to share in the sections that follow. Thank you as always for reading, and please share your thoughts with us [here](#).

Dr. Robert T. Chen  
Scientific Director, Brighton Collaboration

## **I. UPDATES ON GLOBAL OUTBREAKS**

### **COVID-19**

March 13 marked the 4th anniversary of the declaration of the COVID-19 pandemic, and [life has changed drastically](#) for many Americans. While the threat of severe disease has lessened as a result of highly effective vaccinations, the long-term health effects and even social effects have a lasting impact.

COVID continues to produce variants of the Omicron strain that spread rapidly and widely. JN.1 is currently the most common variant detected in new cases in the United States. It was first detected in October 2023 and was estimated to account for 87% of new cases by late March, down slightly. Variants JN.1.13 and JN.1.18 now account for nearly 10% and 2% of COVID cases, respectively. The CDC [data tracking website has bar graphs that show the advance of JN.1](#) and how rapidly it became the dominant cause of new COVID cases. JN.1 is highly contagious, but existing vaccines are still effective against severe disease caused by this variant. As [COVID cases surge](#) and JN.1 immunity builds, it remains to be seen how the next variant will behave. CDC just announced a new subvariant in South Africa. BA.2.87.1: an Omicron subvariant, has caused a few cases since July but it has 30 changes in the spike protein. The relatively few cases suggest that it's not highly transmissible right now. [Cdc tracking BA.2.87.1](#)

[Carlos del Rio's latest summary](#) in JAMA ("COVID-19 in the Fall of 2023—Forgotten but Not Gone") describes the current COVID situation in the US and provides a summary of clinical information.

### **COVID Vaccines**

The US Centers for Disease Control (CDC) [recommends another dose of the 2023 bivalent vaccine for older adults](#), who are at the highest risk of severe disease and hospitalization.

In Autumn 2023, the US Food and Drug Administration (FDA) approved two updated COVID mRNA vaccines ([Moderna, Pfizer Bio-n-Tech](#)) to protect against the XBB.1.5 subvariant of the Omicron variant, as well as the EG.5 and BA.2.86 subvariants. This vaccine is still considered effective for JN.1. A combined COVID plus flu vaccine and a nasal

self-administered flu vaccine, among others, are being studied.

With the development of novel vaccines comes the duty to rigorously assess vaccine safety. The Brighton Collaboration will continue its collaboration with CEPI to update the [list of possible Adverse Events of Special Interest \(AESI\) \(Updated October 2022\)](#) that may be associated with a COVID vaccine. Case definitions and other tools for assessing COVID vaccine AESIs are available.

The FDA commissioner and the head of CBER, which regulates vaccines, [is vaccination approaching a dangerous tipping point comment on the need to override COVID vaccine hesitancy](#) with factual information and clear communication.

### **Prevention**

FDA has just announced [emergency approval of Pemivibart](#) for pre-exposure prophylaxis of Covid-19.

### **COVID-19 Research**

There are now over 400,000 articles in PubMed tagged "COVID-19".

Even as the pandemic enters an endemic phase, we will still be dealing with adverse health effects among those who recovered from acute infections. Long COVID continues to affect some individuals long after the virus has been cleared, with up to 200 million cases reported. Long COVID-19 has also been associated [with cognitive decline](#) in adults, with worse outcomes in individuals who were hospitalized.

Unfortunately, there is no objective test to evaluate the causation of these many symptoms which have been reported to last 3 years or more. [Long COVID may emerge even after acute COVID appears to have cleared](#) and may lead to [significant activity limitations](#) in the long term. [Efforts to clinically define Long COVID cases continue](#). The National Institutes of Health (NIH) recently established the [Office of Long COVID Research and Practice](#), which plans to implement clinical trials to study the effects of different interventions and treatment modalities in preventing Long COVID under the [RECOVER](#).

There is ongoing research to define the pathogenicity of COVID, including several papers that point to

mitochondria as the primary point of attack by the virus, potentially accounting for symptoms of [cardiovascular disease](#), [long COVID](#), and [post-exertional malaise](#). The discovery of [SARS-CoV-2 in the retina](#) shows how widely distributed the virus is in the human body.

## **MPOX**

The CDC reviewed why the [expected increase in Mpox cases did not happen](#). They attribute this favorable change to “lessons learned” from the COVID and HIV pandemics and a change in communication around Mpox vaccination.

## **MEASLES**

Despite [safe and effective vaccines](#), [measles cases increased worldwide](#), with the largest impact on children. [Measle cases are spreading in the US](#)

## **II. VACCINE SAFETY RESEARCH**

### **The BEST Initiative**

The US Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) has formed the [Biologics Effectiveness and SafeTy \(BEST\) Initiative](#) to ensure the safety and effectiveness of biological products. BEST uses new methods such as artificial intelligence and natural language. [A recent publication from](#) Best found no increase in stroke risk after Covid vaccination in older adults [Stroke risk after Covid-19](#)

### **Adverse Events**

New possible adverse events and refinement of previously reported continue to be published. In the largest study to date by the Global Vaccine Data Network (GVDN), possible safety signals for [transverse myelitis and acute disseminated encephalomyelitis after viral vector and mRNA COVID vaccines](#) were identified. A review article summarizes the evidence for and against [neuroimmunological outcomes, including Guillain-Barre and Bell’s Palsy associated with COVID vaccination](#).

However, a recent paper published in Heart shows that cardiac and thromboembolic complications are less frequent following COVID vaccination compared

to SARS-CoV-2 infection, reinforcing the benefits of COVID vaccination relative to the risks. Further studies have shown that [chronic fatigue](#) and [alopecia areata](#) were elevated after COVID disease, suggesting that prevention of SARS-CoV-2 infection could reduce the risks of these sequelae.

A German man who [reportedly received a staggering 217 COVID vaccine doses in 29 months](#), against all recommendations, reported no adverse events following any of the vaccine doses.

Clinical trials of an RSV vaccine candidate for pregnant people were halted due to evidence of an [elevated risk of preterm birth](#) among vaccine recipients compared to controls, despite high vaccine efficacy against severe RSV disease.

## **III. VACCINATION AND SOCIETY**

### **History**

Learn about the [role of animals in human vaccine development](#) throughout history.

### **Vaccination Intentions and Hesitancy**

Communication of the benefits of vaccination is critical to improving vaccine uptake. The American Medical Association is [introducing a series called “Communicating Medicine”](#) to showcase evidence-based practices around communicating health information to patients. The series invites submissions of brief articles.

The [Moderna Atlas website](#) includes resources for vaccine providers to improve vaccine confidence among patients. Register for an account to access [Bench2Practice trainings](#).

Governmental vaccination mandates, a long-standing strategy for infectious diseases prevention, are [facing new challenges](#) with growing vaccine hesitancy. [Religious exemptions](#) and [medical freedoms](#) continue to protect anti-vaccine beliefs and behaviors, and the processes for granting religious exemptions are inconsistent across jurisdictions in the US. In California, a 2019 policy change intended to reduce medical exemptions for vaccination was [successful in this goal, but this benefit was undermined by an increase in children avoiding vaccination requirements](#)

by attending school remotely or homeschooling. [Confidence in scientists to act in the public's best interest](#) has decreased since before the COVID pandemic. Because of poor uptake of COVID, influenza, and RSV vaccines in mid-December, [the CDC issued a plea for increased efforts](#) to immunize as the respiratory infection season in the United States reaches a peak.

Unfortunately, [health disinformation is increasingly hard to combat](#), and vaccine [safety data are often subject to misinterpretation](#). [Lessons learned from the early response to the COVID pandemic](#) suggest that public health agencies and political leaders can retain public trust in the next pandemic by making data-driven decisions and weighing the pros and cons of strict and “illiberal” containment measures.

### **Political Vaccinology**

A proposed NIH program to better understand what health communication works for whom was [paused without explanation](#).

[Citing misinformation, a Florida health official](#) calls for a halt in mRNA vaccine administration.

[Effect of high dose ivermectin](#), a bad idea that won't go away.

### **Caveat Emptor**

Paper retractions have increased markedly recently, perhaps in parallel with the [increase in so-called “paper mills”](#), scientific journals known for rapid publishing of poorly reviewed manuscripts. However, this is not a new phenomenon. In 1923 pharmacologist A.J. Clark lamented [false advertising by makers of proprietary medicines](#), citing a fraudulent tuberculosis treatment that was published in a prominent journal.

Businesses selling unapproved stem cell treatments for COVID are [now targeting individuals with long COVID](#).

[Dana Farber Cancer institute seeks to retract](#) flawed studies.

## **IV. BC MEMBER NEWS & ANNOUNCEMENTS**

### **Brighton Collaboration is on LinkedIn**

Follow [our LinkedIn page](#) to receive the latest updates from the Brighton Community.

### **SPEAC Project: Meet the Experts**

The SPEAC project has published three Q&A features with executive board members, [Dr. Wan-Ting Huang](#), [Dr. Manu Chaudhary](#), and [Dr. Esperança Sevens](#). Read more of [SPEAC's recent news](#).

### **View-hub by IVAC**

[COVID-19 Safety Studies project offers evidence to support increasing active vaccine safety surveillance in low- and middle-income countries](#): The COVID-19 Safety Studies project from the International Vaccine Access Center (IVAC) at Johns Hopkins University offers evidence to support increasing active vaccine safety surveillance in low- and middle-income countries.

Brighton Collaboration spoke with Parisa Shamaeizadeh, MSPH, and Rebecca Chandler MD to learn more about [the disparities they identified and opportunities to create more robust evidence for vaccine safety](#) that will improve public confidence in vaccines.

### **Global Vaccine Data Network (GVDN)**

[99 Million People Included in Largest Global Vaccine Safety Study](#): An impressive coordinated global effort, our partners at Global Vaccine Data Network announced the launch of a new data dashboard that serves as a critical resource for understanding vaccine risks and safety signals. The largest-ever vaccine safety study, these efforts reach beyond what single sites or regions would be able to amass. GVDN's efforts collected data from 99 million people from 10 sites across eight countries providing clear and strong communication to the health sector and public about how we understand vaccine safety.

### **Ongoing case definition translations**

We are excited to announce that the Brighton Collaboration has begun publishing [Korean translations](#) for our case definitions and associated companion guides. Some have been published

previously in [Chinese](#), [Spanish](#), [French](#), and [Portuguese](#).

### **New Brighton Collaboration Publications**

- [Lessons Learned and Key Recommendations from the COVAX Vaccine Safety Working Group](#)
- [Comment: “Serially Combining Epidemiological Designs Does Not Improve Overall Signal Detection in Vaccine Safety Surveillance”](#)
- [Thrombosis with Thrombocytopenia Syndrome \(TTS\) and Vaccine-Induced Immune Thrombocytopenia and Thrombosis \(VITT\) Case Definition](#)

### **BC Membership**

Brighton is looking to expand its membership to strengthen global participation in activities and working groups. Currently, Brighton Collaboration consists of over 1000 members in 108 different countries with the majority of members from the USA, Canada, and India. Please encourage your colleagues to visit our website and [join](#) the Brighton Collaboration.

### **Brighton Collaboration Website**

The BC website is continuously updated with BC news and activities. It also has an archive of BC case definitions and publications on [the new website](#). Please send comments on the new website, and keep an eye out for new content and features on the website as we go forward.

## **V. NEW VACCINE SAFETY LITERATURE**

A PubMed search for “vaccine, adverse event” yields approximately 200 new articles each month. Adding terms sharpens the focus and shortens the list. Here are a few articles that may be of interest.

- Villanueva P, McDonald E, Croda J, et al. Factors influencing adverse events following COVID-19 vaccination. *Hum Vaccin Immunother*. 2024;20(1):2323853. doi:10.1080/21645515.2024.2323853  
<https://pubmed.ncbi.nlm.nih.gov/38445666/>
- An J, Liu Y, Ma Y, et al. Real-world data of China: Analysis of HPV vaccine coverage and post-vaccination adverse reaction monitoring in Western Chinese provinces from 2018 to 2021. *Hum Vaccin Immunother*. 2024;20(1):2315653. doi:10.1080/21645515.2024.2315653  
<https://pubmed.ncbi.nlm.nih.gov/38372046/>
- Serhan M, Psihogios A, Kabir N, et al. A scoping review of active, participant centred, digital adverse events following immunization (AEFI) surveillance of WHO approved COVID-19 vaccines: A Canadian immunization Research Network study. *Hum Vaccin Immunother*. 2024;20(1):2293550. doi:10.1080/21645515.2023.2293550  
<https://pubmed.ncbi.nlm.nih.gov/38374618/>
- Rossier LN, Décosterd NP, Matter CB, et al. SARS-CoV-2 vaccination in inflammatory bowel disease patients is not associated with flares: a retrospective single-centre Swiss study. *Ann Med*. 2024;56(1):2295979. doi:10.1080/07853890.2023.2295979  
<https://pubmed.ncbi.nlm.nih.gov/38289017/>

- Moro PL, Carlock G, Fifadara N, et al. Safety monitoring of bivalent mRNA COVID-19 vaccine among pregnant persons in the vaccine adverse event reporting System - United States, September 1, 2022 - March 31, 2023. *Vaccine*. Published online March 9, 2024. doi:10.1016/j.vaccine.2024.02.084  
<https://pubmed.ncbi.nlm.nih.gov/38462432/>
- Korbal P, Wysocki J, Jackowska T, et al. Phase 3 Safety and Immunogenicity Study of a Three-dose Series of Twenty-valent Pneumococcal Conjugate Vaccine in Healthy Infants and Toddlers. *Pediatr Infect Dis J*. Published online March 8, 2024. doi:10.1097/INF.0000000000004300  
<https://pubmed.ncbi.nlm.nih.gov/38456705/>
- Pullen RH 3rd, Sassano E, Agrawal P, et al. A Predictive Model of Vaccine Reactogenicity Using Data from an In Vitro Human Innate Immunity Assay System. *J Immunol*. 2024;212(5):904-916. doi:10.4049/jimmunol.2300185  
<https://pubmed.ncbi.nlm.nih.gov/38276072/>
- Rivera Mejía L, Peña Méndez L, Bandyopadhyay AS, et al. Safety and immunogenicity of shorter interval schedules of the novel oral poliovirus vaccine type 2 in infants: a phase 3, randomised, controlled, non-inferiority study in the Dominican Republic [published correction appears in *Lancet Infect Dis*. 2024 Jan 3;:]. *Lancet Infect Dis*. 2024;24(3):275-284. doi:10.1016/S1473-3099(23)00519-4  
<https://pubmed.ncbi.nlm.nih.gov/38109921/>

## **BRIGHTON COLLABORATION LEADERSHIP**

### **Brighton Collaboration Science Board**

Here is the [full list of SB members](#) and their qualifications as well as their [Brighton experience and areas of expertise](#).

Paul Henri Lambert, MD - Switzerland  
Azucena Bardaji, MD, MSc, PhD - Spain  
Jim Buttery, MD - Australia  
Alejandro Cravioto, MD, PhD - Mexico  
Matthew Dudley, PhD, MSPH - USA  
Jane Gidudu, MD, MPH - USA  
Hector Izurieta, MD, PhD - USA  
Najwa Khuri-Bulos, MD - Jordan  
Denny Kim, MD, MPH - USA  
Nicola Klein, MD, PhD - USA  
Karina Top, MD, MS, FRCPC - Canada  
Robert Wise, MD - USA

### **Science Board Members Emeritus**

**Barbara J. Law, MD:** Vaccine safety consultant, Pediatric Infectious Disease subspecialist with 10 years of experience as Chief of Vaccine Safety for Public Health Agency of Canada, CAN

**Kathryn M. Edwards, MD:** Vanderbilt University, School of Medicine, Nashville, TN, USA

**Daniel Salmon, BA, MPH, PhD:** Johns Hopkins Bloomberg School of Public Health, Baltimore, MD USA

**Helen Petousis-Harris, PhD:** University of Auckland NZ

**Delese Mimi Darko, MBA:** African Vaccines Regulatory Forum AVAREF, GH

**Sonali Kochhar, MD:** University of Washington, Seattle, USA

**Wan-Ting Huang, MD:** Safety Platform for Emergency vAccines (SPEAC), Taipei, Taiwan

**Clare Cutland, PhD, MBBCH:** University of Witwatersrand, South Africa

**Nicholas Wood, MBBS, PhD, MPH, FRACP:** National Centre for Immunisation Research and Surveillance Australia

**Brighton Collaboration Secretariat**

**Robert Chen, MD, MA:** Scientific Director

**Eileen Farnon MD:** Research Director

**Anita Renhan-White:** Deputy Director

**Adriana Gibby:** Program Manager

**Caroline Cassard:** Communications Manager

**Frederick Varricchio, MD, PhD:** Editor in Chief ([varricchio@comcast.net](mailto:varricchio@comcast.net))

**Nadja Vielot, PhD:** Associate Editor

**Robert Chen, MD, MA:** Scientific Director, Brighton Collaboration

**Karin Batty:** Correspondent for Oceania

**Publisher**

**Brighton Collaboration**  
The Task Force for Global Health  
330 West Ponce de Leon Avenue  
Decatur, Georgia 30030 USA

**VSO Editorial Board**